CLAIMS

What is claimed is:

1. An implantable system, comprising:

a housing;

energy delivery circuitry provided in the housing;

detection circuitry provided in the housing;

one or more subcutaneous electrodes configured for subcutaneous, non-intrathoracic placement in a patient and coupled to the energy delivery and detection circuitry;

a lead interface provided on the housing and coupled to the energy delivery and detection circuitry, the lead interface configured to receive at least one lead comprising one or more lead electrodes, the one or more lead electrodes configured for intrathoracic placement in the patient; and

a controller provided in the housing and coupled to the lead interface and the energy delivery and detection circuitry, the system operable in a first configuration using the one or more subcutaneous electrodes in the absence of the at least one lead and operable in a second configuration using at least the one or more lead electrodes, the system capable of providing cardiac activity sensing and stimulation in each of the first and second system configurations, respectively.

2. The system according to claim 1, wherein the system is configurable to operate in the first configuration using only the one or more subcutaneous electrodes.

3. The system according to claim 1, wherein the system is configurable to operate in the second configuration using only the one or more lead electrodes.

4. The system according to claim 1, wherein the system is configurable to operate in the second configuration using selected ones of the subcutaneous and lead electrodes.

5. The system according to claim 1, further comprising a can electrode provided at the housing, the system configurable to use the can electrode in one or both of the first and second configurations.

6. The system according to claim 1, wherein a unipolar configuration is selectable in the second configuration for one or more of sensing, pacing, and shocking using a selected one of the lead electrodes and a selected one of the subcutaneous electrodes.

7. The system according to claim 1, further comprising a switching matrix coupled to the detection and energy delivery circuitry, the subcutaneous electrodes, and to the lead electrodes via the lead interface, the controller configuring the switching matrix to couple selected ones of the lead and subcutaneous electrodes with selected inputs or outputs of the detection and energy delivery circuitry.

8. The system according to claim 1, further comprising a switching matrix coupled to the detection and energy delivery circuitry, the subcutaneous electrodes, and to the lead electrodes via the lead interface, the controller configuring the switching matrix to couple selected ones of the lead and subcutaneous electrodes with selected inputs and outputs of the detection and energy delivery circuitry to perform a capture threshold determination.

9. The system according to claim 1, wherein the lead interface comprises one or both of a ventricular lead interface and an atrial lead interface.

10. The system according to claim 1, wherein the lead interface comprises one or both of a pacing lead interface and a defibrillation lead interface.

11. The system according to claim 1, wherein the lead interface comprises a bi-ventricular lead system interface or a multi-site lead system interface.

12. The system according to claim 1, wherein the lead interface comprises one or more of a transvenous lead interface, an endocardial lead interface, and an epicardial lead interface.

13. The system according to claim 1, wherein the controller configures the system to selectively operate in one of the first and second configurations in response to a signal received from a patient-external signal source.

14. The system according to claim 1, wherein the controller configures the system to operate in one of the first and second configurations, and, in response to a predetermined condition, configures the system to operate in the other of the first and second configurations.

15. The system according to claim 14, wherein the predetermined condition comprises a predetermined heart rhythm.

16. The system according to claim 14, wherein the predetermined condition comprises an arrhythmia, unsuccessful detection of an arrhythmia, or treatment of an arrhythmia.

17. The system according to claim 14, wherein the predetermined condition comprises expiration of a predetermined duration of time or occurrence of a scheduled event.

18. The system according to claim 1, wherein the controller configures the system to operate concurrently in the first and second configurations.

19. The system according to claim 1, wherein the controller configures the system to switch operation between the first and second configurations to detect a heart rhythm or treat an arrhythmia using each of the first and second configurations.

20. The system according to claim 1, wherein:

at least two of the lead electrodes are disposed in a single heart chamber; and

the second configuration provides one or both of multisite sensing and multisite energy delivery.

21. The system according to claim 1, wherein the controller:

configures the system to operate in one of the first and second configurations to perform a first function; and

configures the system to operate in the other of the first and second configurations to perform a second function, wherein performance of the first function enhances performance of the second function.

22. The system according to claim 21, wherein the first function comprises a first energy delivery function to instill organization in an arrhythmia, and the second function comprises a second energy delivery function to terminate the arrhythmia.

23. The system according to claim 1, wherein:

the at least one lead comprises an atrial lead; and

the controller configures the system to provide one or both of bradycardia pacing and antitachycardia pacing.

24. The system according to claim 1, wherein:

the at least one lead comprises an atrial lead;

the second configuration provides atrial activity sensing and atrial arrhythmia therapy delivery; and

the first configuration provides backup ventricular tachyarrhythmia therapy support for the second configuration.

25. The system according to claim 1, wherein:

the at least one lead comprises an atrial lead having one or more atrial electrodes; and

the controller configures the system to operate in the first configuration to provide tachyarrhythmia discrimination using the one or more subcutaneous electrodes and the one or more atrial electrodes.

26. The system according to claim 1, wherein the housing defines a unitary structure, and each of the subcutaneous electrodes is respectively provided on the housing.

27. The system according to claim 1, wherein the controller determines a transthoracic impedance using at least two of the electrodes.

28. The system according to claim 27, wherein the controller detects disordered breathing using the transthoracic impedance.

29. The system according to claim 1, wherein the controller acquires electrocardiograms for storage in a memory coupled to the controller.

30. The system according to claim 1, wherein the controller acquires diagnostics for storage in a memory coupled to the controller.

31. The system according to claim 1, further comprising a communications device coupled to the controller, the communications device configured for communicating with a patient-external programmer or a patient-external network system.

32. An implantable system, comprising:

a housing;

energy delivery circuitry provided in the housing;

detection circuitry provided in the housing;

one or more subcutaneous electrodes configured for subcutaneous, non-intrathoracic placement in a patient and coupled to the energy delivery and detection circuitry;

a lead interface provided on the housing and coupled to the energy delivery and detection circuitry, the lead interface configured to receive at least one lead comprising one or more lead electrodes, the one or more lead electrodes configured for intrathoracic placement in the patient; and

a controller provided in the housing and coupled to the lead interface and the energy delivery and detection circuitry, the system operable in a first configuration using the one or more subcutaneous electrodes in the absence of the at least one lead and operable in a second configuration using at least the one or more lead electrodes, the system capable of providing cardiac activity sensing and stimulation in each of the first and second system configurations, respectively, the system configurable to perform a particular function in each of the first and second configurations and to acquire performance data associated with performance of the particular function in each of the first and second configurations.

33. The system according to claim 32, wherein the particular function comprises a function associated with sensing.

34. The system according to claim 32, wherein the particular function comprises a function associated with tachyarrhythmia detection.

35. The system according to claim 32, wherein the particular function comprises a function associated with bradycardia detection.

36. The system according to claim 32, wherein the particular function comprises a first sub-function associated with rate-based tachyarrhythmia detection and a second sub-function associated with morphology-based tachyarrhythmia detection.

37. The system according to claim 32, wherein the particular function comprises a function associated with one or both of stimulus waveform generation and stimulus waveform delivery.

38. The system according to claim 32, wherein the particular function comprises a function involving a configuration of one or both of the lead electrodes and the subcutaneous electrodes.

39. The system according to claim 32, wherein the housing defines a unitary structure, and each of the subcutaneous electrodes is respectively provided on the housing.

40. The system according to claim 32, further comprising a communications device coupled to the controller, the communications device configured for communicating with a patient-external programmer or a patient-external network system.

41. A cardiac sensing and stimulation method, comprising:

providing an implantable cardiac stimulation device operable in a first configuration and a second configuration, the first configuration using one or more subcutaneous electrodes configured for subcutaneous, non-intrathoracic placement in a patient for sensing cardiac activity and delivering cardiac stimulation therapy, the second configuration using at least one lead for sensing cardiac activity and delivering cardiac stimulation therapy, the at least one lead comprising one or more lead electrodes configured for intrathoracic placement in the patient;

operating the cardiac stimulation device in the first configuration in the absence of the at least one lead; and

enabling operation of the cardiac stimulation device in the second configuration at least in part by coupling the at least one lead to the cardiac stimulation device.

42. The method according to claim 41, wherein the first and second configurations support cardioversion/defibrillation modes.

43. The method according to claim 41, wherein the first and second configurations support pacing modes.

44. The method according to claim 41, wherein one of the first and second configurations supports a pacing mode, and the other of the first and second configurations support a cardioversion/defibrillation mode.

45. The method according to claim 41, further comprising enabling the first and second configurations for concurrent operation.

46. The method according to claim 41, further comprising selectively enabling and disabling the first and second configurations for sequential operation.

47. The method according to claim 41, further comprising selectively enabling and disabling the first and second configurations for tiered operation during an arrhythmic event.

48. The method according to claim 41, further comprising selectively enabling and disabling the first and second configurations from a patient-external location.

49. The method according to claim 41, further comprising storing performance information acquired when operating in each of the first and second configurations.

50. The method according to claim 49, further comprising transmitting the performance information to a patient-external location.

51. The method according to claim 49, further comprising producing comparison data using the performance information, the comparison data comprising data indicative of performance when operating in one of the first and second configurations relative to the other of the first and second configurations.

52. The method according to claim 41, further comprising operating in one of the first and second configurations as a primary operating configuration, and operating in the other of the first and second configurations in response to a performance anomaly detected while operating in the primary operating configuration.

53. The method according to claim 41, further comprising:

performing a first function while operating in one of the first and second configurations; and

performing a second function while operating in the other of the first and second configurations, wherein performance of the first function enhances performance of the second function.

54. The method according to claim 53, wherein the first function comprises a first energy delivery function to instill organization in an arrhythmia, and the second function comprises a second energy delivery function to terminate the arrhythmia.

55. The method according to claim 41, further comprising:

performing a particular function when operating in each of the first and second configurations; and

acquiring performance data associated with performance of the particular function when operating in each of the first and second configurations.

56. The method according to claim 55, wherein the particular function comprises a function associated with sensing.

57. The method according to claim 55, wherein the particular function comprises a function associated with tachyarrhythmia detection.

58. The method according to claim 55, wherein the particular function comprises a function associated with bradycardia detection.

59. The method according to claim 55, wherein the particular function comprises a first sub-function associated with rate-based tachyarrhythmia detection and a second sub-function associated with morphology-based tachyarrhythmia detection.

60. The method according to claim 55, wherein the particular function comprises a function associated with stimulus waveform generation or stimulus waveform delivery.

61. The method according to claim 55, wherein the particular function comprises a function involving a configuration of one or both of the lead and the one or more subcutaneous electrodes.

62. The method according to claim 55, further comprising storing performance information associated with performance of the particular function when operating in each of the first and second configurations.

63. The method according to claim 62, further comprising transmitting the performance information to a patient-external location.

64. The method according to claim 62, further comprising producing comparison data using the performance information, the comparison data comprising data indicative of performance when operating in one of the first and second configurations relative to the other of the first and second configurations.

65. The method according to claim 41, further comprising:

intrathoracically sensing atrial activity and, in response to conditions necessitating atrial therapy, delivering atrial stimulation therapy intrathoracically; and

providing transthoracic ventricular tachyarrhythmia backup therapy in response to conditions necessitating ventricular therapy sensed while delivering atrial stimulation therapy.

66. The method according to claim 41, further comprising:

sensing atrial activity; and

providing one or both of bradycardia pacing and antitachycardia pacing based at least in part on the sensed atrial activity.

67. The method according to claim 41, wherein the second configuration supports one or both of multisite sensing and multisite energy delivery with respect to a single heart chamber or multiple heart chambers.

68. The method according to claim 41, wherein providing the cardiac stimulation device comprises providing software for operating the cardiac stimulation device in the first configuration and the second configuration.

69. The method according to claim 41, further comprising modifying, subsequent to providing the cardiac stimulation device, software in the cardiac stimulation device for operation in the second configuration, the modified software enabling the cardiac stimulation device to operate in the second configuration after coupling the at least one lead to the cardiac stimulation device.

70. The method according to claim 41, further comprising:

operating the cardiac stimulation device in the second configuration in the absence of the one or more subcutaneous electrodes; and

enabling operation of the cardiac stimulation device in the first configuration at least in part by coupling the one or more subcutaneous electrodes to the cardiac stimulation device.

71. The method according to claim 70, further comprising modifying, subsequent to providing the cardiac stimulation device, software in the cardiac stimulation device for operation in the first configuration, the modified software enabling the cardiac stimulation device to operate in the first configuration after coupling the one or more subcutaneous electrodes to the cardiac stimulation device.

72. The method according to claim 41, further comprising modifying operation of the cardiac stimulation device in response to a change in a patient's cardiac condition.

73. The method according to claim 41, further comprising enabling one or more sensing, diagnostic, or therapeutic features in response to a change in a patient's cardiac condition.

74. The method according to claim 41, further comprising determining a capture threshold of one or more heart chambers when operating in the first or second configurations.

75. The method according to claim 41, further comprising measuring a transthoracic impedance using at least two of the electrodes.

76. The method according to claim 75, further comprising detecting disordered breathing using the transthoracic impedance.

77. The method according to claim 41, further comprising storing electrocardiograms when operating in the first configuration.

78. A cardiac sensing and stimulation system, comprising:

means for sensing cardiac activity;

means for generating a cardiac stimulation therapy,

means for coupling at least one lead to the sensing and generating means when operating the system in a second configuration, the at least one lead comprising one or more lead electrodes configured for intrathoracic placement;

means for enabling operation of the system in the second configuration in response to the coupling means receiving the at least one lead;

means for operating the system in a first configuration using subcutaneous, non-intrathoracic electrodes coupled to the sensing and generating means in the absence of the at least one lead; and

means for sensing cardiac activity and delivering the cardiac stimulation therapy in each of the first and second configurations.

79. A cardiac sensing and stimulation system, comprising:

means, using only subcutaneous, non-intrathoracic electrodes, for sensing cardiac activity and delivering cardiac stimulation therapy in a first configuration;

means, using selected ones of intrathoracic and the non-intrathoracic electrodes, for sensing cardiac activity and delivering cardiac stimulation therapy in a second configuration;

means for performing a particular function when operating in each of the first and second configurations; and

means for acquiring performance data associated with performance of the particular function when operating in each of the first and second configurations.

80. The system according to claim 79, further comprising means for producing comparison data using the performance information, the comparison data comprising data indicative of performance when operating the system in one of the first and second configurations relative to the other of the first and second configurations.

81. An implantable system, comprising:

a housing;

energy delivery circuitry provided in the housing;

detection circuitry provided in the housing;

a switching matrix provided in the housing and coupled to the detection and energy delivery circuitry, the switching matrix comprising first and second electrode connection arrangements, the first electrode connection arrangement configured for coupling with one or more subcutaneous, non-intrathoracic electrodes and the second electrode connection arrangement configured for coupling with one or more intrathoracic electrodes; and

a controller provided in the housing and coupled to the switching matrix and the energy delivery and detection circuitry, the controller configuring the system to operate in a first configuration by enabling only the first electrode connection arrangement and to operate in a second configuration by enabling at least the second electrode connection arrangement.

82. The system of claim 81, wherein the controller configures the system to operate in the second configuration by enabling the first and second electrode connection arrangements.

83. The system of claim 81, wherein the controller configures the switching matrix to enable selected electrode connections of the first and second electrode connection arrangements.

84. The system of claim 81, wherein the controller configures the switching matrix to couple selected electrode connections of the first and second electrode connection arrangements with selected inputs or outputs of the detection and energy delivery circuitry.

85. The system of claim 81, wherein one or both of the first and second electrode connection arrangements comprises a lead interface, the lead interface facilitating mating engagement with a cardiac lead or module.

86. The system of claim 81, wherein the first and second electrode connection arrangement comprises a lead interface, the lead interface facilitating mating engagement with a cardiac lead or module.

87. The system of claim 81, wherein the first or second configuration comprises a cardiac activity monitoring-only configuration.

88. The system of claim 81, wherein the first or second configuration comprises a cardiac energy delivery configuration.

89. The system of claim 81, wherein each of the first and second configurations comprise a cardiac monitoring and energy delivery configuration.

90. An implantable system, comprising:

a housing;

energy delivery circuitry provided in the housing;

detection circuitry provided in the housing;

an interface provided on the housing and coupled to the energy delivery and detection circuitry, the interface configured to receive at least one intrathoracic electrode arrangement and at least one subcutaneous non-intrathoracic electrode arrangement; and

a controller provided in the housing and coupled to the interface and the energy delivery and detection circuitry, the system operable in a first configuration using only the subcutaneous non-intrathoracic electrode arrangement, in a second configuration using only the intrathoracic electrode arrangement, and in a third configuration using the non-intrathoracic and intrathoracic electrode arrangements, the system capable of providing cardiac activity sensing and stimulation in each of the first, second, and third system configurations, respectively.

91. The system of claim 90, wherein the system is operable only in the first configuration in the absence of connectivity between the intrathoracic electrode arrangement and the interface.

92. The system of claim 91, wherein coupling the intrathoracic electrode arrangement to the interface enables operation of the system in the second configuration or the third configuration.

93. The system of claim 90, wherein the system is operable only in the second configuration in the absence of connectivity between the subcutaneous non-intrathoracic electrode arrangement and the interface.

94. The system of claim 93, wherein coupling the subcutaneous non-intrathoracic electrode arrangement to the interface enables operation of the system in the first configuration or the third configuration.

95. A cardiac sensing and stimulation method, comprising:

providing an implantable cardiac stimulation system operable in a first configuration, a second configuration, and a third configuration, the first configuration using only a subcutaneous non-intrathoracic electrode arrangement, the second configuration using only an intrathoracic electrode arrangement, and the third configuration using the non-intrathoracic and intrathoracic electrode arrangements, the system capable of providing cardiac activity sensing and stimulation in each of the first, second, and third system configurations, respectively;

enabling the cardiac stimulation system for operation only in the first configuration in the absence of connectivity between the intrathoracic electrode arrangement and the cardiac stimulation device and with connectivity established between the subcutaneous non-intrathoracic electrode arrangement and the cardiac stimulation device;

enabling the cardiac stimulation system for operation only in the second configuration in the absence of connectivity between the subcutaneous, non-intrathoracic electrode arrangement and the cardiac stimulation device and with connectivity established between the intrathoracic electrode arrangement and the cardiac stimulation device; and

enabling the cardiac stimulation system for operation in the first, second or third configuration with connectivity established between the cardiac stimulation device and each of the subcutaneous non-intrathoracic electrode arrangement and the intrathoracic electrode arrangement.